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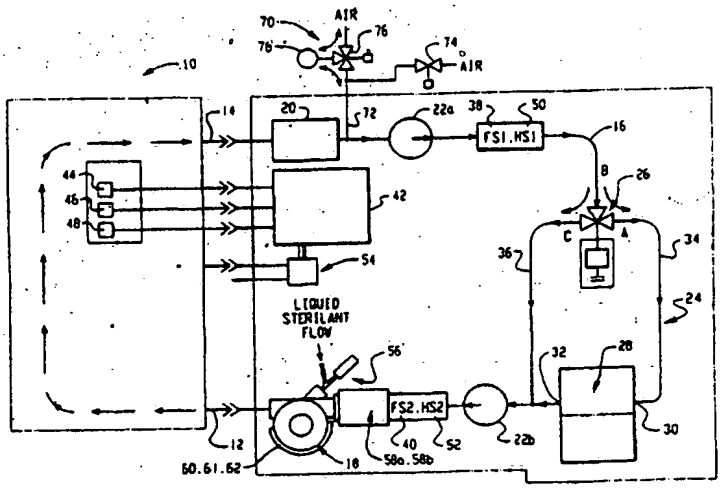

(57) Abstract

A vaporizer (18) vaporizes liquid hydrogen peroxide or other liquid sterilants to generate a decontaminant vapor. Heaters (60, 61, 62) control the temperature of the decontaminant vapor and a carrier gas such as air. The sterilant vapor passes from the vaporizer through an inlet port (12) of a sealable chamber (10), through the chamber, through an outlet port (14) and through a fluidic circuit (16) from the outlet port back to the inlet port. A converter (20) breaks down the hydrogen peroxide into water. Blowers (22a, 22b) circulate the carrier gas through the fluidic circuit. Monitors (44, 46, 48, 54) monitor temperature, relative himidity, vapor concentration, and pressure within the chamber. A processor (42) controls a pressure fine-tuning unit (70) which adds or removes air to adjust pressure and controls an adjustable dryer (24) in accordance with the monitored temperature, relative humidity, and vapor concentration.

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CONTINUOUS-OPERATION, CLOSED-LOOP DECONTAMINATION SYSTEM AND METHOD

Background of the Invention

The present application relates to a system and method of vapor phase decontamination. It finds particular application in flow-through or closed-loop type systems and will be described with particular reference thereto.

Reusable medical, pharmaceutical, and biological instruments are generally sterilized before each use. Additionally, reusable containers employed in medical, pharmaceutical, and biological applications, such as gloves and incubators, are generally sterilized before each use. In facilities and applications where these types of instruments and containers are used several times a day, it is important to achieve sterilization efficiently and economically. Several methods have been developed for delivering a vapor phase sterilant to an enclosure or chamber for sterilizing a load or the anterior thereof. In one option, the "deep vacuum" approach, a deep vacuum on the order of a Torr or less is used to pull a liquid sterilant into a heat vaporizer. Once vaporized, the sterilant vapor is drawn into an evacuated and sealed chamber. In another option, the "flow-through" approach, the sterilant vapor is mixed with a carrier gas that carries the sterilant vapor into, through, and out of the chamber. The chamber is generally near atmospheric pressure, but may be at either a positive or negative pressure.

U.S. Patent No. 4,956,145 which issued September 11, 1990, discloses a deep vacuum method of vapor phase sterilization in which a predetermined concentration of

hydrogen peroxide vapor is maintained in an evacuated, sealed chamber. The amount of sterilant vapor injected into the chamber is regulated or adjusted to account for the decomposition of hydrogen peroxide sterilant vapor into water and oxygen in the closed system over time. In another approach, illustrated in U.S. Patent Nos. 5,445,792 and 5,508,009, a predetermined percent saturation is maintained in an open, flow-through sterilization. The rate of hydrogen peroxide vapor injection into the carrier gas is regulated or adjusted in response to predetermined characteristics of the carrier gas. Also, other systems have been developed for conducting vapor phase sterilization. An open flow-through system designed to handle the disposition of residual sterilant vapors is disclosed in U.S. Patent No. 4,909,999, issued March 20, 1990.

U.S. Patent No. 5,173,258, issued December 22, 1992 discloses another flow-through system in which vapor phase hydrogen peroxide is introduced into a recirculating, closed-flow of carrier gas. The hydrogen peroxide vapor is introduced and maintained at a preselected concentration selected to optimize the sterilization cycle. A dryer dehumidifies the recirculating flow, preferably to at least about 10% relative humidity to prevent moisture build-up resulting from the decomposition of hydrogen peroxide vapor over time. By eliminating moisture build-up, the system can maintain the sterilization chamber at higher concentrations of hydrogen peroxide vapor for longer periods of time. The predried gas accepts more sterilant vapor. Further, to avoid condensation of the sterilant vapor, the relative humidity in the chamber is preferably reduced, to at least about 10%, prior to introducing the sterilant vapor. After decomposition is complete, the enclosure may be rehumidified or conditioned if desired for the selected application. Although the foregoing methods and systems provide effective sterilization cycles, there exists a need for further improvement and greater sterilization efficiency.

Summary of the Invention

In accordance with the present invention, a closed-loop, flow-through vapor phase decontamination system is provided. A sealable chamber has an inlet port and an outlet port. A closed-loop fluidic circuit has a first end fluidicly connected with the chamber inlet port and a second end fluidicly connected with the chamber outlet port. The fluidic circuit provides a path for recirculating a carrier gas into, through, and out of the chamber. A means circulates the gas through the closed-loop fluidic circuit. A vaporizer is fluidicly connected to the fluidic circuit adjacent to the inlet port for delivering a decontaminant vapor into the recirculating carrier gas. A monitor monitors for at least two of temperature, relative humidity, and decontaminant vapor concentration in the chamber. An adjustable dryer is fluidicly connected with the fluidic circuit upstream from the vaporizer for selectively drying the recirculating gas entering the vaporizer. A processor receives outputs from the monitor and controls the dryer in accordance therewith.

In accordance with another aspect of the present invention, a method of closed-loop, flow-through vapor phase decontamination is provided. A carrier gas is recirculated into an inlet port of a sealable chamber, through the chamber, out an outlet port of the chamber, and from the outlet port around a closed-loop fluidic circuit back to the inlet port. A decontaminant vapor is delivered into the recirculating carrier gas upstream from the chamber inlet port. At least two of temperature, relative humidity, and decontaminant vapor concentration in the chamber are monitored. The carrier gas is selectively dried upstream from the delivery of the decontaminant vapor in accordance with the monitored temperature, relative humidity, and decontaminant vapor concentration to maintain a preselected percent saturation of the decontaminant vapor in the chamber.

One advantage of the present invention is that it improves sterilization efficiency.

Another advantage of the present invention resides in its improved consistency and sterilization assurance.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art on reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is a graph showing exemplary D-values of a range of hydrogen peroxide concentrations;

FIGURE 2 is a graph showing exemplary D-values of a range of hydrogen peroxide percent saturations;

FIGURE 3 is a graph showing the sterilant concentrations and sterilant percent saturations over a sterilization cycle for a prior closed, flow-through prior sterilization method, which maintains a predetermined sterilant vapor concentration;

FIGURE 4 is a graph showing the sterilant concentrations and sterilant percent saturations over a sterilization cycle for the sterilization method of the present invention, which maintains a predetermined sterilant vapor percent saturation;

FIGURE 5 is a graph comparing the bacterial kill rates over a sterilization cycle for the sterilization methods of FIGURES 3 and 4;

FIGURE 6 is a schematic illustration of one embodiment of the continuous-operation, closed-loop flow-through system of the present invention;

FIGURE 7 is a schematic illustration of another embodiment of the continuous-operation, closed-loop flow-through system of the present invention;

FIGURE 8 is a schematic illustration of the liquid decontaminant vaporizer, including vaporizer heaters; and,

FIGURE 9 is a cutaway portion of the illustration of FIGURES 7 and 8, schematically illustrating the carrier gas preheaters in series.

Detailed Description of the Preferred Embodiments

The term "decontamination" shall be understood to include sterilization, disinfection, and sanitization. For the purpose of describing the preferred embodiments herein the objective discussed will be sterilization.

The sterilant vapor preferably comprises hydrogen peroxide generated from 30-35% by weight aqueous hydrogen peroxide solution. The carrier gas preferably comprises air. It is contemplated that other condensible gas sterilants and other inert gas carriers, such as nitrogen, may also be used. For purposes of describing the preferred embodiments, the carrier gas and the sterilant vapor discussed will be respectively air and vapor phase hydrogen peroxide generated from an aqueous hydrogen peroxide solution.

In the method, a flow of carrier gas is recirculated in a closed-loop conduit circuit that leads into, through, and out of a sealable sterilization chamber. A liquid sterilant is vaporized and delivered into the carrier gas flow entering the chamber, and then converted to a form suitable for disposal after exiting the chamber, i.e., water and oxygen in the case of hydrogen peroxide sterilant.

The method succeeds in optimizing sterilization by monitoring the chamber temperature, relative humidity, and vapor concentration. The carrier gas is then only partially and selectively dried in response to these parameters to maintain a predetermined percent of sterilant vapor saturation in the sterilization chamber. Percent saturation is defined as the ratio between actual sterilant vapor concentration and the sterilant vapor dewpoint concentration.

In the method of the present invention, the water vapor concentration of the carrier gas entering the chamber may be higher than was previously obtained or desired. Yet, superior kill potentials and more efficient sterilization can be obtained.

The improvement provided by the present invention can be appreciated by inspecting FIGURES 1 and 2. FIGURE 1 illustrates the relationship between the D-value for Bacillus sterothermophilus and hydrogen peroxide sterilant vapor concentrations ranging from 1.5 mg/l to 3.7 mg/l. The percent saturation is held constant at 80%. As indicated, the sterilization efficacy approximately doubles (the D-value is halved) when the concentration is doubled.

Prior closed, flow-through systems recognized the foregoing relationship and attempted to maximize the concentration of sterilant vapor in the carrier gas flowing into the sterilization chamber. The mount of sterilant that can be injected into a carrier gas is limited, however, by dewpoint considerations. TABLE 1 shows the dewpoint concentrations for 35% hydrogen peroxide that is flash vaporized (as described in U.S. Patent No. 4,642,165, incorporated by reference herein) into an enclosure with the given temperature and relative humidity air:

TABLE 1: Dewpoint Concentration for H_2O_2 Vapor

	Enclosure Relative Humidity			
Enclosure Temperature	0%	10%	20%	30%
15°C	1.103	0.903	0.731	0.585
20°C	1.562	1.284	1.044	0.839
25°C	2.184	1.805	1.477	1.185
30°C	3.008	2.497	2.051	1.651
35°C	4.097	3.410	2.810	2.270
40°C	5.485	4.599	3.803	3.081

FIGURE 2 illustrates the relationship between the D-value for Bacillus sterothermophilus and hydrogen peroxide vapor concentration is maintained at 1.6 mg/l. As indicated, the sterilization efficacy nearly quadruples (the D-value goes from 4 to almost 1) when the sterilant vapor percent saturation is slightly more than doubled. By controlling percent saturation independently of concentration, the present invention obtains significantly improved sterilization.

FIGURES 3-5 also illustrate the improved results obtained with the present invention. FIGURE 3 illustrates a

typical sterilant vapor and percent saturation plot for a prior sterilization cycle which seeks to maximize concentration. FIGURE 4 illustrates a typical sterilant vapor and percent saturation plot for the present invention. The percent saturation is below 70% during the first half of the prior sterilization cycle. In the present invention, the percent saturation is only below 70% for the first ten minutes of the sterilization cycle and is at about 90% for most of the cycle.

The kill potential for a sterilization cycle can be determined by plotting the instantaneous kill rate versus time for a sterilization cycle and calculating the area under the curve. Using the D-values from FIGURE 2 and the curve from FIGURES 3 and 4, the kill rates for the prior system and the present invention are plotted in FIGURE 5. The cross-hatch area shows the significantly improved kill potential for the present invention.

The method of the invention will now be described with further reference to the exemplary system illustrated in FIGURE 6. As shown, the flow-through vapor phase sterilization system of the invention includes a sealable chamber **10** having an inlet port **12** and an outlet port **14**. A conduit or fluidic circuit **16** is fluidly connected to the chamber ports to provide a closed-loop flow path for recirculating a carrier gas into, through, and out of the chamber **10**.

The system also includes a liquid sterilant vaporizer unit **18** for delivering a vaporized liquid sterilant into the carrier gas flow. The vaporizer unit **18** is fluidly connected to the conduit circuit between the drying unit and the chamber inlet port. Liquid sterilant is preferably atomized in an atomizer **56** fluidly connected to the vaporizer **18** and delivered to the vaporizer in the form of a fine mist to increase the likelihood of complete vaporization.

As illustrated in FIGURES 7 and 8, a series of spaced vaporizer heaters **60**, **61**, **62** of decreasing wattage are preferably employed to provide a heat gradient from the top to the bottom of the vaporizer **18** when a heat-sensitive vapor,

such as hydrogen peroxide vapor, is the sterilant. Most of the flash vaporization of the liquid/mist sterilant occurs at the top of the tortuous path **64** of the vaporizer. As the liquid/vapor mixture descends through the tortuous path, heaters of lower wattage provide less heat at the middle and bottom of the vaporizer, so as not to degrade already-formed vapor, and to vaporize any remaining liquid. Preferably, the heaters are spaced and controllable in groups of two (**60a** and **60b**; **61a** and **61b**; **62a** and **62b**). For example, where there is a high rate of flow of air and vapor through the vaporizer, all the heaters may be on. When there is a low rate of flow, some of the heaters may selectively be turned off.

In addition, the system includes a converter **20** for converting the sterilant vapor to a form suitable for disposal, and fluidly connected to the conduit circuit downstream of the chamber outlet port **14**. When the sterilant vapor is hydrogen peroxide, the converter **20** preferably comprises a catalytic converter for decomposing hydrogen peroxide to water and oxygen.

The system also includes a blowing unit **22a** and **22b** and an adjustable drying unit **24**, each fluidly connected to the conduit circuit. The blowing unit serves to push or force the carrier gas around the closed-loop flow path. As illustrated in FIGURE 7 and described further below, the system includes an additional chamber pressure fine-tuning unit **70**, fluidly connected to the conduit circuit, that may be used to fine-tune the pressure in the flow path by adding minute quantities of atmospheric air or removing minute quantities of the carrier gas in the conduit circuit. This unit is preferably employed when carrier gas flows having high flow rates are used and the unit may be used to fine-tune the pressure in the enclosure without changing the speed of the blowers of the blowing unit.

At least one heater **58** is fluidly connected to the conduit circuit downstream from the drying unit **24** for controlling the temperature of the carrier gas entering the vaporizer **18**. As illustrated in FIGURES 7 and 9, preferably at least two heaters **58a** and **58b** of different wattage, fluidly

connected in series, are provided. The heaters are independently controllable by the processing unit **42** (described below), based on the sensed carrier gas flow rate by the flow sensor **40** and the known rate of sterilant injection into the vaporizer. Therefore, the heaters can selectively be activated to preheat the carrier gas to a desired temperature. For example, in low flow rate conditions (less than 20 SCFM) and/or low injection rates, a low wattage heater is selectively turned on. In medium flow rate conditions (20-40 SCFM) and/or injection rates, a higher wattage heater may be selectively used. In higher low rate conditions (40-70 SCFM), a combination of high and low wattage heaters may be selectively used. The heaters may also be pulsed ON and OFF by the processor, in response to a sensed temperature by temperature sensor **44**, to maintain a desired temperature of the carrier gas.

The adjustable drying unit **24** serves selectively to remove moisture from the carrier gas flow entering the chamber. The drying unit preferably comprises a variable valve **26** having a first flow path **A-B** and a second flow path **B-C**, and a regenerative air dryer **28** having an inlet port **30** and an outlet port **32**. The air dryer **28** is positioned downstream of the variable valve **26**. A first fluid flow line **34** connects the first flow path to the dryer inlet port **30**, while a second fluid flow line **36** bypasses the dryer **28** and connects to the conduit circuit downstream of the drying unit. By varying the amount of flow through the first and second valve flow paths, a selected portion of the carrier gas flow can be routed to bypass the dryer **28**. Alternately, a rate of drying, e.g., condensing of water vapor, by the dryer **28** can be adjusted directly. In this way, the humidity of the carrier gas can be regulated or adjusted (i.e., the carrier gas can be selectively dried) to maintain a predetermined percent saturation of sterilant vapor in the chamber as the sterilization cycle proceeds.

A first humidity sensor **50** is positioned downstream of the converter **20** to measure the absolute humidity of the air flow exiting the converter **20**. A second humidity sensor

52 is positioned downstream of the air dryer 28 to measure the absolute humidity of the air flow exiting the air dryer 28. Assuming, for example, that the air stream exiting the converter has a humidity of 11.5 mg/l and the air dryer reduces the humidity of the air stream that passes through it to 2.3 mg/l, the humidity of the air stream entering the vaporizer can be calculated as reported in TABLE 2.

TABLE 2

Fraction Bypassed	Fraction Dried	Air Stream Absolute Humidity (Humidity Sensor 52 reading)
0	1.0	2.3 mg/liter
.1	.9	3.22
.2	.8	4.14
.3	.7	5.06
.4	.6	5.98
.5	.5	6.9
.6	.4	7.82
.7	.3	8.74
.8	.2	9.66
.9	.1	10.58
1.0	0	11.5 mg/liter

The blowing unit preferably comprises a first blower 22a positioned upstream and a second blower 22b positioned downstream of the drying unit. More preferably, the blowers can be adjusted based on feedback from flow sensors 38 and 40 to provide a slightly negative or positive pressure within the sterilization chamber 10 as monitored by a pressure transducer 54.

The chamber pressure fine-tuning unit 70, illustrated in FIGURE 7, preferably comprises an air line 72, positioned upstream of blower 22a, fluidly connecting the conduit circuit to atmospheric air via two-way valve 74 and three-way valve 76. Three-way valve 76 is fluidly connected to a pump 78. When the pressure adjusting unit is not being used, valve 74 is closed and valve 76 is toggled to be closed to the carrier gas stream in the conduit circuit. When a minute quantity of carrier gas is to be removed from carrier gas steam path and pump 78 withdraws a small amount of air

from the process air stream. When a minute quantity of atmospheric air is to be added to the carrier gas stream, valve **76** is closed and valve **74** is momentarily opened. The adding and removing processes may be continued in a see-saw fashion until the point of desired enclosure pressure is reached, at which time the pressure fine-tuning unit is deactivated. The activation or deactivation of the unit is processor controlled based on feedback from at least pressure sensor **54**.

In addition, the system includes a processing unit **42** for monitoring the following three parameters within the sterilization chamber during sterilization: 1) the temperature, 2) the relative humidity, and 3) the sterilant vapor concentration. The processing unit also determines or selects the degree of drying of the carrier gas in response to these three parameters, to maintain a predetermined percent saturation of the sterilant vapor during sterilization.

The processing unit may include a temperature sensor **44**, relative humidity sensor **46**, and a vapor concentration sensor **48** positioned within the chamber **10** to monitor directly the internal chamber temperature, relative humidity, and vapor concentration. Alternatively, the processing unit may include means for monitoring these parameters indirectly. The vapor concentration can be indirectly monitored through calculations based on the measured air-flow rate and sterilant vapor injection rate. The relative humidity can be indirectly monitored by using the humidity sensor **50** positioned downstream of the converter to measure the absolute humidity of the exiting air flow. The background humidity is subtracted from that value. A standard water vapor dewpoint chart can then be consulted to provide the relative humidity for the difference at the chamber temperature.

Preferred embodiments of the invention are further illustrated by the following examples, in which an aqueous 35% hydrogen peroxide solution was flash vaporized:

Example 1

The chamber temperature is 35°C, relative humidity is 20%, and sterilant vapor concentration is 2.27 mg/l. Reference to TABLE 1 or another available dewpoint concentration chart shows that the sterilant dewpoint concentration is 2.810 mg/l. The percent saturation is therefore 80%.

According to the present invention, the humidity of the carrier gas entering the chamber is adjusted by repositioning the variable valve to bypass a larger fraction of air so that the relative humidity of the enclosure becomes 30%. According to the dewpoint concentration chart, the dewpoint concentration is now 2.27 mg/l. The percent saturation then becomes 100%.

Example 2

The chamber temperature is 40°C and the sterilant vapor concentration is 3.081 mg/l, calculated based on the air flow rate and the sterilant delivery rate. Humidity sensor 50 indicates that the absolute humidity in the returning air stream is 15.94 mg/l. For the flash vaporized sterilant, the aqueous solution contributes 10.22 mg/l humidity or (65/35)x3.081 mg/l. Subtracting this value from the absolute humidity results in 15.94-5.72 mg/l. = 10.22 mg/l background humidity. Referring to a dewpoint chart, at 40°C this results in 20% relative humidity. At 40°C and 20% relative humidity, the sterilant vapor dewpoint concentration is 3.803 mg/l. This means that the calculated percent saturation is 81%.

The variable valve is repositioned to bypass a larger fraction of air flow around the air dryer. The background humidity in the returning air stream at dewpoint conditions at 40°C for a 3.081 mg/l hydrogen peroxide vapor concentration according to TABLE 1 is 30%. The absolute humidity corresponding to a 30% background relative humidity is found as follows:

AH = (65/35)x3.081 mg/l + 15.35 mg/l = 21.08 mg/l.

Repeating the above calculations for the new absolute humidity shows that the percent saturation is 100%. Thus, by

increasing the carrier gas humidity from 20% to 30%, the chamber reaches 100% sterilization, greatly improving the sterilization.

Example 3

Blower **22b** is adjusted based on feedback from the flow sensor **40** to provide an air flow rate of 50 CFM. Blower **22b** is adjusted to provide a lower air flow rate. The rotational speed of blower **22a** is increased (or decreased) based upon the reading from the pressure transducer **54**. A slightly positive (0.2 in WC $\leq P \leq 2$ in WC) pressure is thus maintained in the semi-sealed enclosure while maintaining the desired air flow rate, sterilant vapor concentration and percent saturation.

Example 4

Blower **22a** is adjusted based on feedback from the flow sensor **38** to provide an air flow rate of 50 CFM. Blower **22b** is adjusted to provide a lower air flow rate. The rotational speed of the blower is increased (or decreased) based upon the reading from the pressure transducer **54**. A slightly negative (02 in WC $\leq P \leq -0.13$ in WC) pressure is thus maintained in the semi-sealed enclosure while maintaining the desired air flow rate, sterilant vapor concentration and percent saturation.

CLAIMS:

Having thus described the preferred embodiment, the invention is now claimed to be:

1. A closed-loop, flow-through vapor phase decontamination system including a sealable chamber (10) having an inlet port (12) and an outlet port (14), a closed-loop fluidic circuit (16) having a first end fluidicly connected with the chamber inlet port and a second end fluidicly connected to the chamber outlet port provides a path for recirculating a carrier gas into, through, and out of the chamber (10), a means (22a, 22b) for circulating gas through the closed-loop fluidic circuit, a vaporizer (18) fluidicly connected to the fluidic circuit adjacent the inlet port (12) for delivering a decontaminant vapor into the recirculating carrier gas, characterized by:

a monitor (44, 46, 48) for monitoring at least two of temperature, relative humidity, and decontaminant vapor concentration in the chamber (10);

an adjustable dryer (24) fluidicly connected with the fluidic circuit (16) upstream from the vaporizer (18) for selectively drying the recirculated gas entering the vaporizer;

a processor (42) which receives outputs from the monitor (44, 46, 48) and controls the dryer (24) in accordance therewith.

2. The system as set forth in claim 1, further characterized by:

the vaporizer having an internal tortuous path between a carrier gas receiving entrance and the inlet port to the sealable chamber;

a heating means (60, 61, 62) disposed along and external to the tortuous path, the heating means being operated to control a heat of the decontaminant vapor and carrier gas.

3. The system as set forth in either of preceding claims 1 and 2, further characterized by:

a line (72) fluidicly connected between the fluidic loop and an external source of carrier gas;

a valve (76) connected with the line for controlling the passage of carrier gas therethrough;

a monitor (54) for monitoring chamber pressure;

the processor (42) further controlling the valve (76) in accordance with the monitored chamber pressure for selectively adding and removing carrier gas from the fluidic circuit (16) in accordance with the monitored pressure.

4. The system as set forth in claim 3, further including a pump (78) connected with the line for supplying carrier gas thereto under pressure.

5. The apparatus as set forth in any one of preceding claims 1-4, further characterized by:

a converter (20) disposed upstream from the vaporizer for converting the decontaminant vapor to a form suitable for disposal.

6. A method of closed-loop, flow-through vapor phase decontamination including recirculating a carrier gas into an inlet port (12) of a sealable chamber (10), through the sealable chamber, out an outlet port (14) of the sealable chamber, and from the outlet port of the sealable chamber around a closed-loop fluidic circuit (16) back to the inlet port of the sealable chamber, delivering (18) a decontaminant vapor into the recirculating carrier gas upstream from the chamber inlet port, characterized by:

monitoring (44, 46, 48) at least two of temperature, relative humidity, and decontaminant vapor concentration in the chamber;

selectively drying (24) the carrier gas upstream from delivery of the decontaminant vapor in accordance with the monitored temperature, relative humidity, and

decontaminant vapor concentration to maintain a predetermined percent saturation of the decontaminant vapor in the chamber.

7. The method as set forth in claim 6, further characterized by:

heat vaporizing (18) a decontaminant liquid to form the decontaminant vapor;

heating (60, 61, 62) a portion of the fluidic circuit between drying the carrier gas and the chamber inlet to control at least one of (i) temperature of the carrier gas and decontaminant vapor and (ii) a temperature gradient approaching the chamber inlet port.

8. The method as set forth in either of claims 6 and 7, further characterized by:

monitoring pressure (54) in the chamber;

selectively introducing and removing carrier gas (70) in accordance with the monitored pressure.

9. The method as set forth in any one of preceding claims 6, 7, and 8, further characterized by:

the carrier gas being air and the decontaminant vapor being hydrogen peroxide vapor and further including converting (20) the hydrogen peroxide vapor to water vapor for disposal upstream of the vaporizer.

10. The method as set forth in any one of preceding claims 6-9, further characterized by:

the selective drying including adjusting a fraction of carrier gas and decontaminant vapor flowing through the fluidic circuit which passes through a dryer (28).

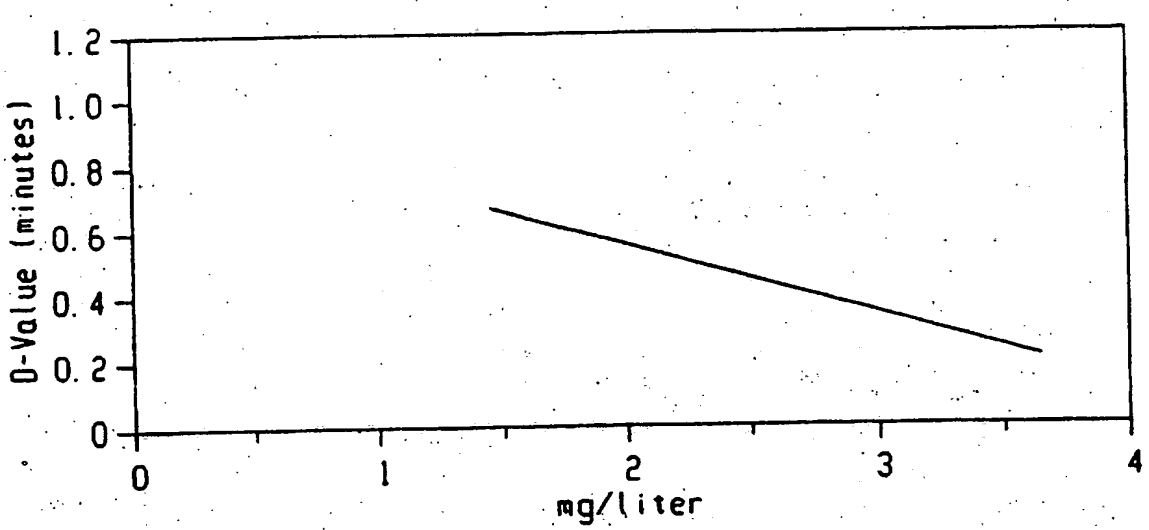
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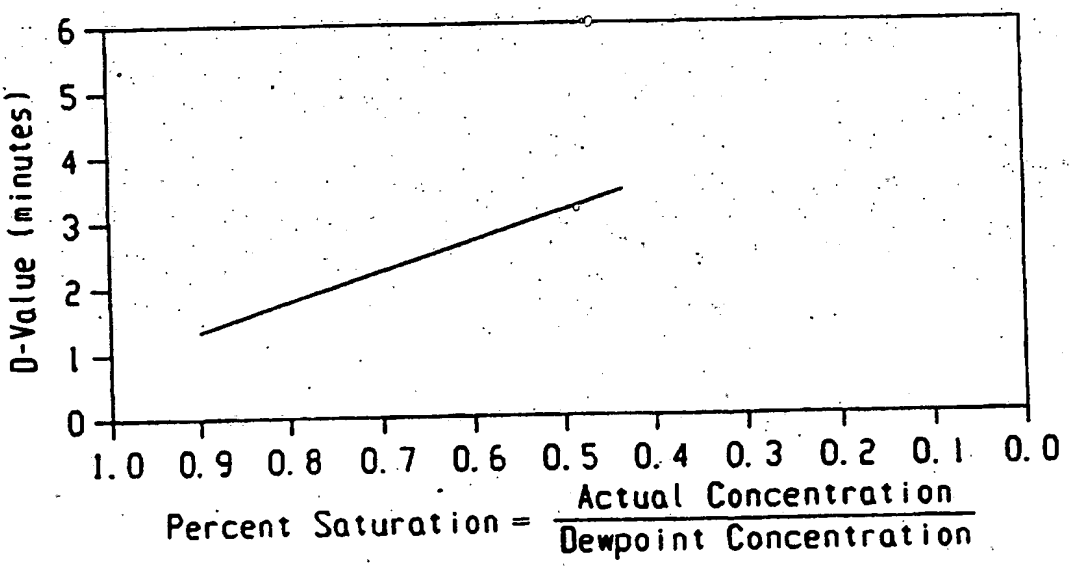
Fig. 1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1
0
D-Value (minutes)
1.0 0.9 0.8 0.7 0.6 0.5 0.4 0.3 0.2 0.1 0.0
Percent Saturation = Actual Concentration / Dewpoint Concentration

Fig. 2

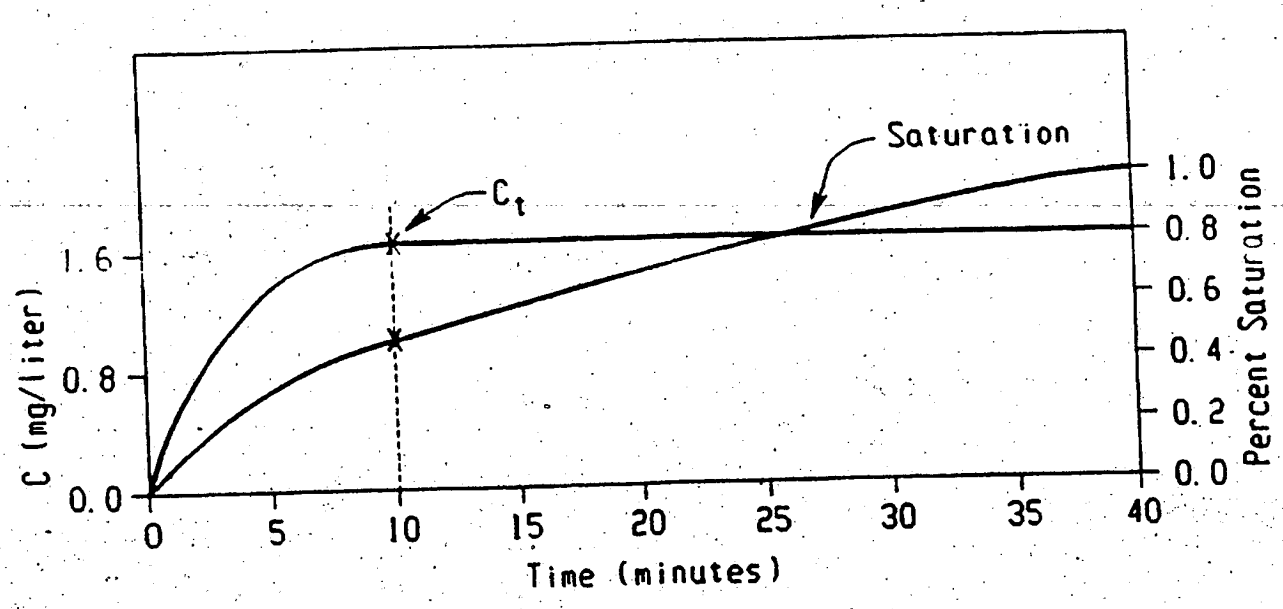
Saturation
C_t
C (mg/liter)
1.6
0.8
0.0
0
5
10
15
20
25
30
35
40
Time (minutes)
1.0
0.8
0.6
0.4
0.2
0.0
Percent Saturation

Fig. 3

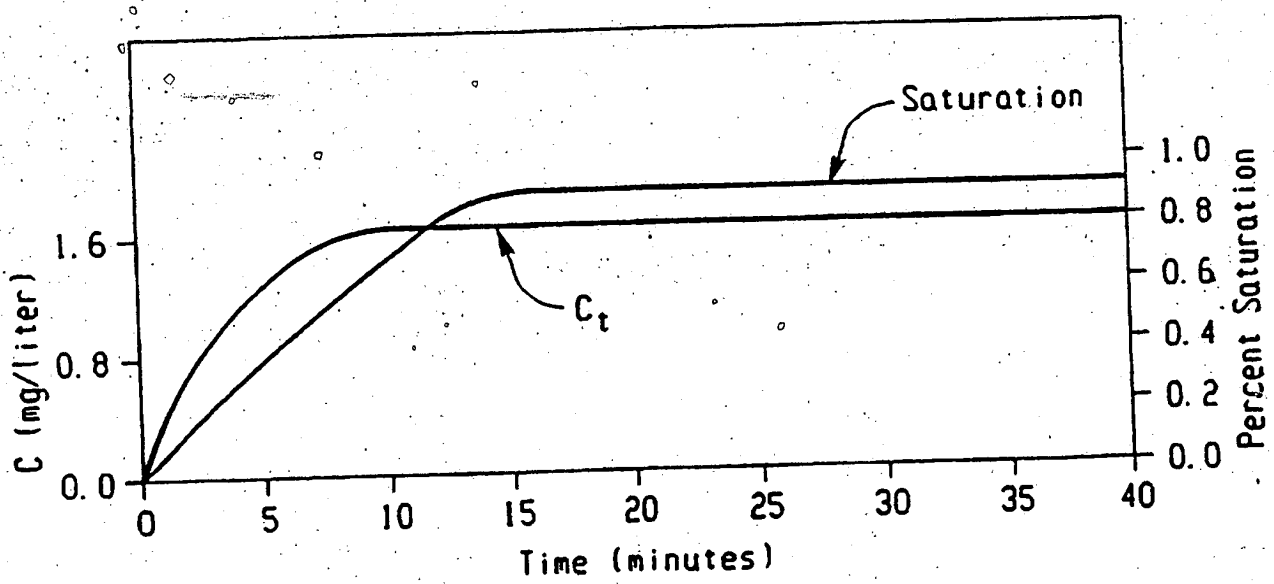
Saturation
C_t
C (mg/liter)
1.6
0.8
0.0
0
5
10
15
20
25
30
35
40
Time (minutes)
1.0
0.8
0.6
0.4
0.2
0.0
Percent Saturation

Fig. 4

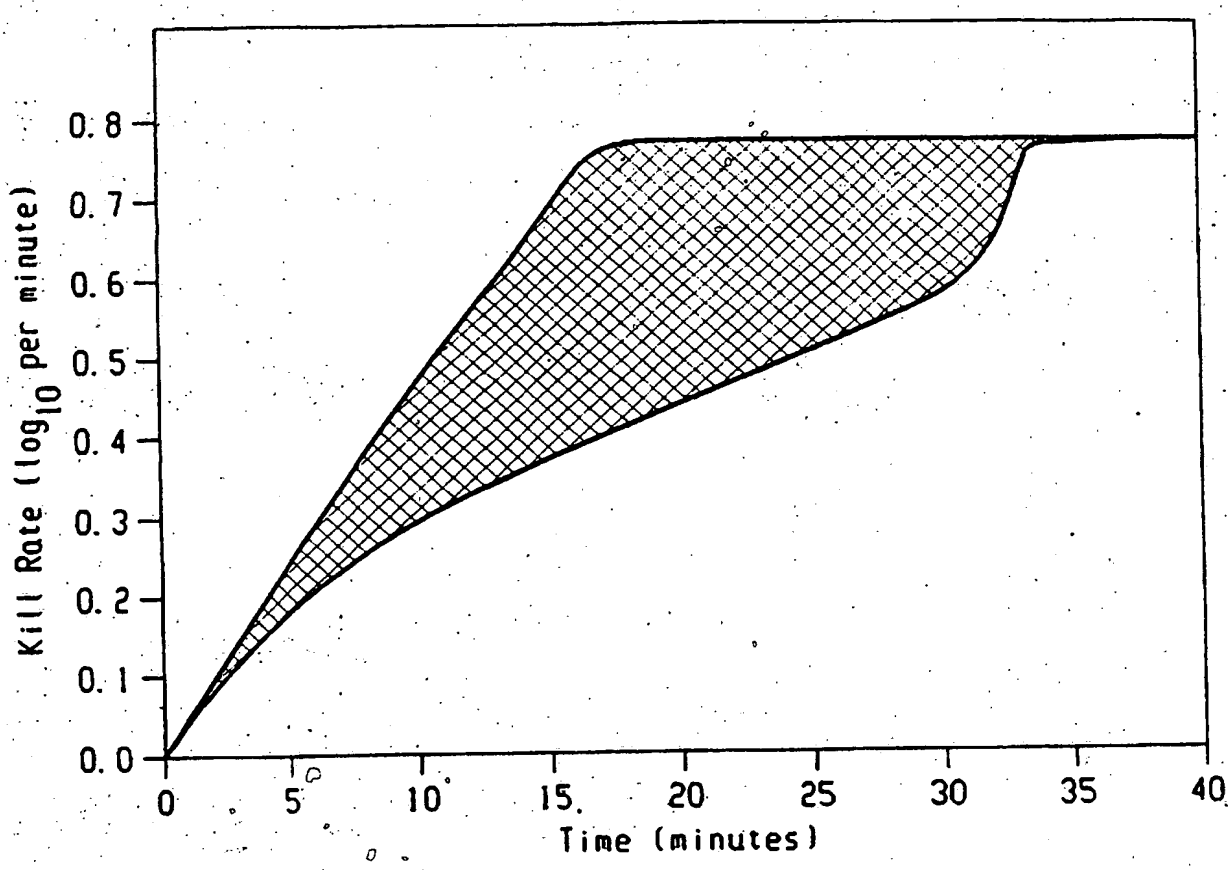
Kill Rate (log_{10} per minute)
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
5
10
15
20
25
30
35
40
Time (minutes)

Fig. 5

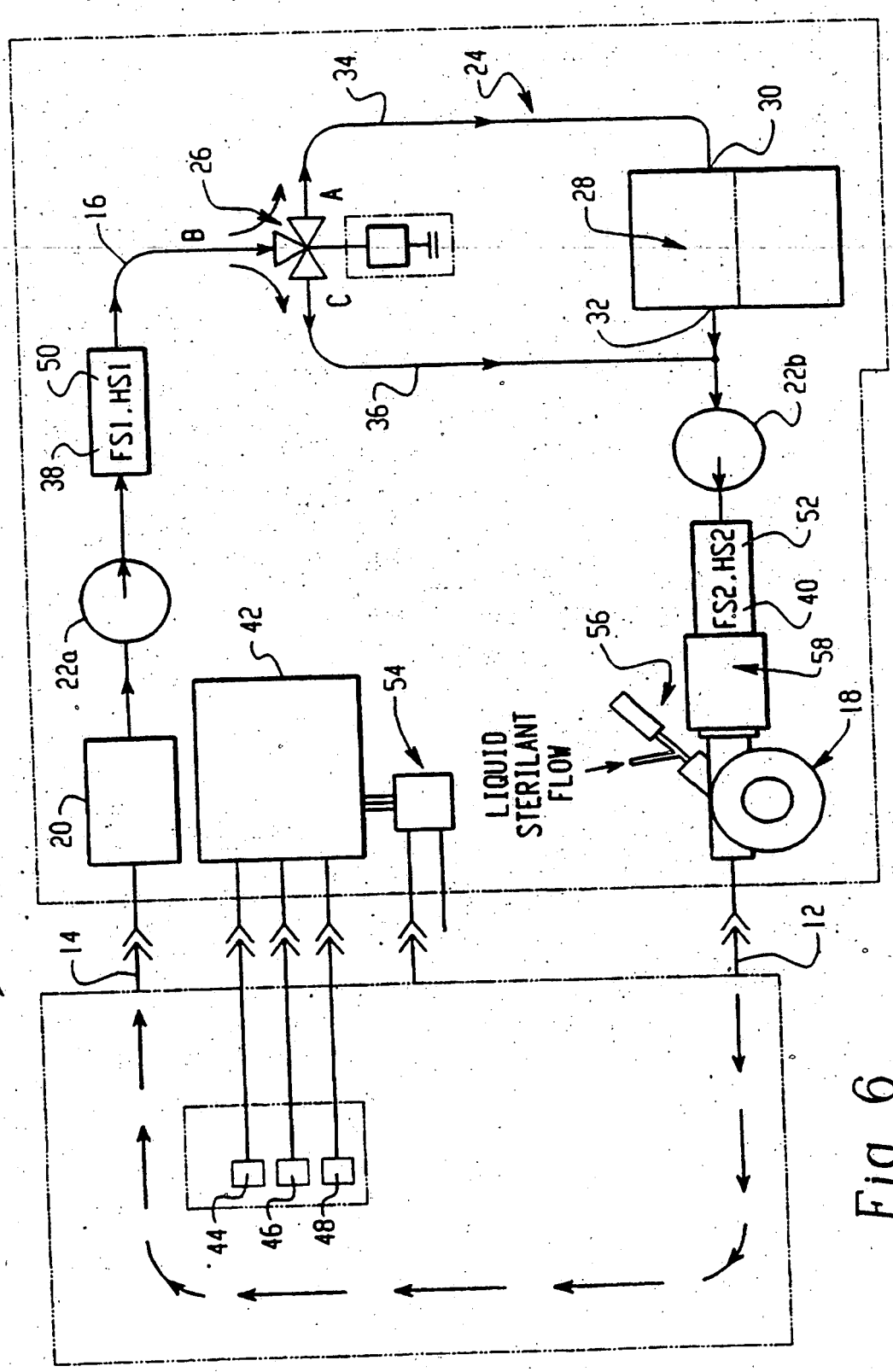
10
12
14
16
18
20
22a
22b
24
26
28
30
32
34
36
38
40
42
44
46
48
50
52
54
56
58
A
B
C
FS1.HS1
FS2.HS2
LIQUID
STERILANT
FLOW

Fig. 6

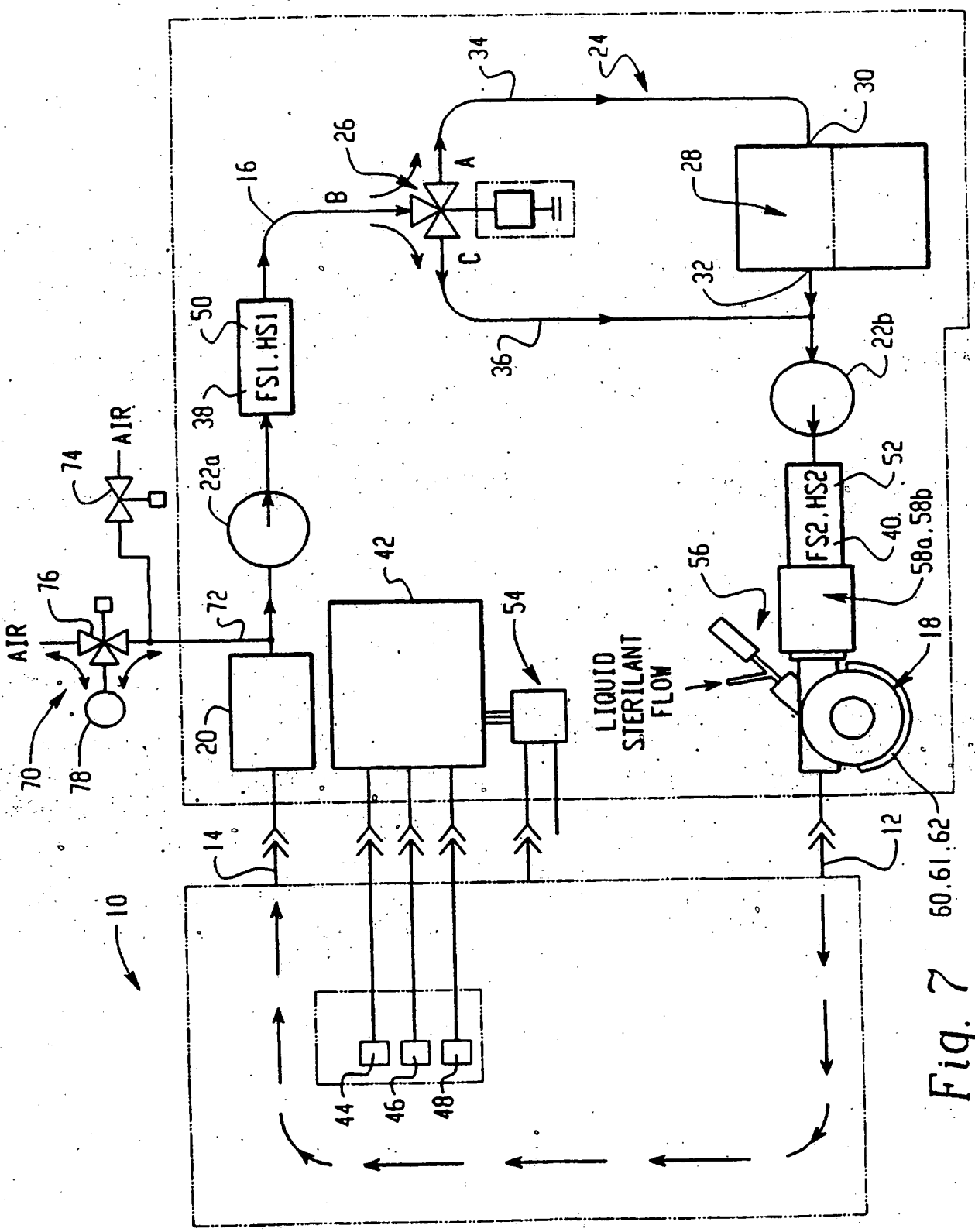
AIR
AIR
LIQUID STERILANT FLOW
FS1.HS1
FS2.HS2
A
B
C
10
12
14
16
18
20
22a
22b
24
26
28
30
32
34
36
38
40
42
44
46
48
50
52
54
56
58a.58b
60.61.62
70
72
74
76
78

Fig. 7

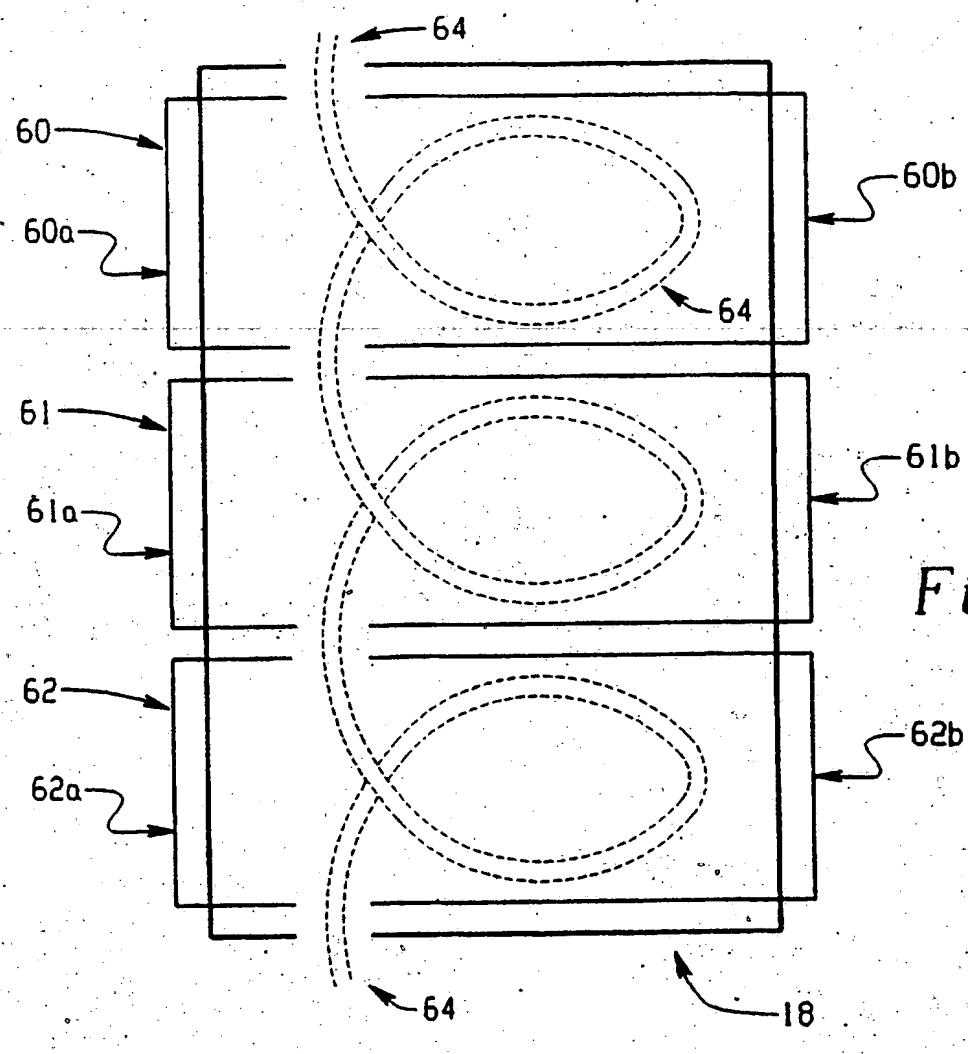
64
60
60a
60b
64
61
61a
61b
62
62a
62b
64
18

Fig. 8

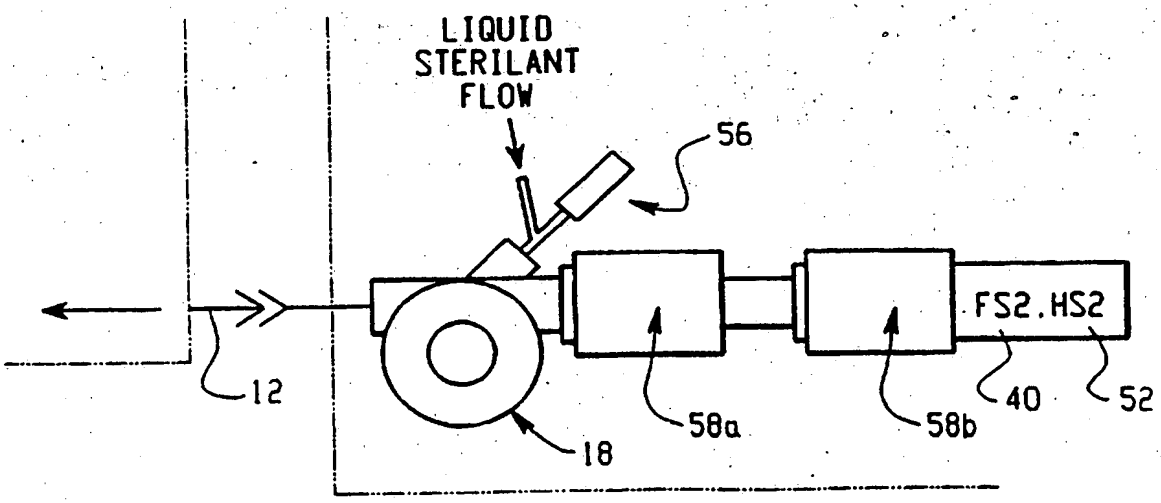
LIQUID
STERILANT
FLOW
56
FS2.HS2
12
58a
58b
40
52
18

Fig. 9

INTERNATIONAL SEARCH REPORT

Internatio· ' Application No
PCT/Us 97/10423

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L2/20 A61L2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 0 774 263 A (MDH LTD) 21 May 1997 see claims ---	1,2,6,7
Y	US 5 445 792-A (RICKLOFF JAMES R ET AL) 29 August 1995 cited in the application see claims; figure 1 ---	1-10
Y	WO 91 05573 A (AMERICAN STERILIZER CO) 2 May 1991 see claims; figures & US 5 173 258 A cited in the application --- -/--	1-10

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
5 November 1997	11. 11. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	ESPINOSA, M

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INTERNATIONAL SEARCH REPORT

Internatic * Application No
PCT/US 97/10423

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 89 06140 A (AMERICAN STERILIZER CO) 13 July 1989 see claims & US 4 956 145 A cited in the application	1-10
A	WO 88 04939 A (AMERICAN STERILIZER CO) 14 July 1988	
A	US 4 992 247 A (FOTI ROBERT C) 12 February 1991	
A	EP 0 298 694 A (AMERICAN STERILIZER CO) 11 January 1989 & US 4 909 999 A cited in the application	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 97/10423

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0774263 A	21-05-97	GB 2308066 A	18-06-97
US 5445792 A	29-08-95	US 5508009 A	16-04-96
WO 9105573 A	02-05-91	US 5173258 A	22-12-92
		DE 69029660 D	20-02-97
		DE 69029660 T	24-04-97
		EP 0486623 A	27-05-92
WO 8906140 A	13-07-89	US 4956145 A	11-09-90
		CA 1317737 A	18-05-93
		CN 1033941 A	19-07-89
WO 8804939 A	14-07-88	US 4863688 A	05-09-89
		CA 1297404 A	17-03-92
		DE 3778355 A	21-05-92
		EP 0294418 A	14-12-88
		JP 1502722 T	21-09-89
		US 4935371 A	19-06-90
US 4992247 A	12-02-91	NONE	
EP 0298694 A	11-01-89	CA 1303811 A	23-06-92
		CN 1032297 A	12-04-89
		DE 3884689 D	11-11-93
		DE 3884689 T	10-02-94
		JP 1070059 A	15-03-89
		US 4909999 A	20-03-90